The New Hampshire Department of Health and Human Services

Expedited Review/Exempt Study Form

Principal Investigator (PI): _____CPHS#:_____
(CPHS use only)

PI's Phone #_____ PI's e-mail:_____

Institution: _____

Study Title: _____

_____

Funding source: _____

Coordinator: _____ Coordinator's Phone#:_____

Coordinator's e-mail_____

Does this project involve: (select reply)

Minors	☐ **Yes** ☐ **No**	**Estimated number of males:**	**_____**
Pregnant women	☐ **Yes** ☐ **No**		
Legally incapacitated adults	☐ **Yes** ☐ **No**	**Estimated number of females:**	**_____**
Prisoners	☐ **Yes** ☐ **No**		

_____ _____
Signature Principal Investigator **Date**

Signature Department Chairperson or PI's Supervisor*

*Signature indicates the investigator has: a) the expertise to carry out the protocol; and b) the support of his or her institution in this endeavor.

Introduction: Explain the purpose of the study including the hypothesis to be tested.
Describe the study procedures, data collection and analysis process.

Location of study: List all locations where the study will take place. Provide the FWA number for each site for any federally funded research. Include in the submission packet a letter of support for each site. It is the policy of the CPHS to not begin a review until a letter of support is in place for at least one site. Research cannot begin at a site until the CPHS has received a letter of support, reviewed it, and approved the site.

Duration of study: Provide an estimate of the dates.

Participants: List inclusion and exclusion criteria. Provide an explanation of the process for recruiting subjects including:

- Which categories of research personnel are designated to obtain informed consent, such as physicians, study coordinators, or research assistants; and
- A description of any process involving "finder fees" or incentives, such as bonus payments or gift certificates, to research personnel for enrollment of subjects
- If chart review is used to identify individuals to recruit, see Attachment A for Medical Records/Chart Review Research

Provide an explanation of the rationale for the involvement of minors, prisoners, pregnant women, or legally incapacitated adults. **Note**: Special classes may require full committee review, contact CPHS for further information.

NIH guidelines require that research involving human participation include minorities and both genders. The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with rationale for its choice. If a certain population is being excluded from the study, please provide a rationale for this exclusion.

Describe the payments that will be made to subjects, including the purpose, amounts, and schedule.

Risks: Describe any potential risks (physical, psychological, social, legal, or other), and assess their likelihood and seriousness. Describe the procedure for protecting against or minimizing any potential risks. Provide a description of how subjects' confidentiality will be maintained. Will a certificate of confidentiality be required?

Risk – Benefit Analysis: Provide a statement of why the risks to subjects are believed to be reasonable in relation to the anticipated benefits to subjects or society.

Informed Consent: Explain how informed consent will be obtained. Describe the methods used to screen potential subjects to determine whether they understand the details of the consent form and what will occur if a potential subject does not comprehend the consent. Attach copies of consent form or information sheet if applicable. Please contact CPHS office for sample consent form if signed consent is to be obtained.

Federal regulations allow for waiver of informed consent and waiver of documentation of informed consent in special circumstances. Please see:

Attachment A for Medical Records/Chart Review Research
Attachment B for Waivers of Informed Consent
Attachment C for Waiver of Documentation of Informed Consent

Potential Conflict of Interest for Investigator:

Describe the financial relationship between the PI and commercial sponsor and whether any compensation is affected by the study outcome. Is payment made directly to the PI or to the institution employing the PI? If applicable, what is the amount of payment per participant?

Acknowledge if any of the following potential conflicts exist and state the member(s) of the research team involved:

The PI, immediate family of the PI, or the institution employing the PI has any proprietary interests in the product including but not limited to patents, trademarks, copyrights, and licensing agreements.

The PI, research staff, or an immediate family member of the PI or research staff has equity interest in the sponsor company greater than $10,000 or 5% ownership.

The PI, research staff, or an immediate family member of the PI or research staff receives payments of other sorts from the sponsor company greater than $10,000 per year in excess of reimbursement of study costs including but not limited to: grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria. If such exists, describe the specific arrangements for payment.

Submit this form to the CPHS office. Be sure to also include:

- A copy of any grant application or protocol for the same study submitted to the U. S. Department of Health and Human Services or FDA, if applicable;
- A copy of the investigator brochure(s), if applicable;
- A copy of the consent form pursuant to He-M 206.05;
- Letters of support from the community organizations or institutions where the study is to be carried out;
- Copies of written materials used in the study and to which subjects might be exposed, such as assessment tools that are not standard, scripts, treatment manuals that are not standard, advertisements; or handouts.
- Documentation that the PI and other research staff have completed training in human subjects protections.

Attachment A
Medical Records/Chart Review Research

Information for Researchers: In research involving the review of patient medical information it is important to ensure the highest standards of maintaining privacy. This form is based on the recently enacted HIPAA legislation (Health Insurance Portability and Accountability Act) and was created to ensure compliance with these regulations.

Identifiable Protected Health Information: Any health information, created or received by a covered entity (health plans, health care clearinghouses, and health care providers) in any form, that identifies an individual and is related to the past, present, or future physical or mental health of the individual, provision of health care to the individual or payment for health care provided to the individual.

Whenever PHI is collected it is important to collect only the ***minimal amount necessary*** in order to conduct the research project.

COMPLETE ITEMS 1 and 2 FOR ALL MEDICAL RECORD/CHART REVIEW PROJECTS:

1. Describe the data fields necessary for research or send a copy of the data recording tool:

2. State whether identifiable protected health information (PHI) will be disclosed (released) outside of the covered entity holding the data? (Note: This release does not refer to publication [which should not contain any patient identifiable information], rather, it refers to PHI being collected for release to an entity outside of the institution or center where the data originates [e.g. data analysis, archiving].

☐ YES ☐ NO
If yes, explain to whom:

CATEGORIES OF REVIEW [Check as appropriate]:

☐ **A. "Review Preparatory to Research":** This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study. By submitting this form the "pre" researcher assures that:

- The use or disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research.
- PHI will not be removed from the covered entity holding the data.
- The PHI for which access is sought is necessary for the review preparatory for research.

If your project involves **Review Preparatory to Research** as described above you have now completed the required information. Please sign the form and submit to the CPHS office. Otherwise continue below.

☐ B. "De-identified Health Information (DHI) "Review the list on the last page of this form. (Note: If using Statistical Waiver include report from the statistician with this form.)
Check as appropriate:
☐ There is or will be a link established with De-identified data in order to trace back to PHI.
☐ There is no and will be no link established with De-identified data. No trace ability to PHI is possible.

If your project involves **De-Identified Data** as described above you have now completed the required information. Please sign the form and submit to the CPHS office. Otherwise continue to #3.

COMPLETE ITEMS 3 and 4 FOR ALL OTHER PROJECTS

3. Describe the plan to protect the data from improper use and disclosure:

4. Describe the plan to destroy the identifiers at the earliest opportunity, unless there is a health or research justification for retaining the identifiers:

☐ **C. "Limited Data Set"** Review the list on the last page of the form. If the project will not collect data elements on the "not allowed" list, then the project involves only the collection of data elements listed in the limited data set.

Check as appropriate:

☐ There is or will be a link established with the Limited Data Set in order to trace back to PHI.
☐ There is no and will be **no** link established with the Limited Data Set. No trace ability to PHI is possible.

If your project involves a **Limited Data Set** you have now completed the required information. Please sign both this form and the Data Use Agreement on the last page. Submit the form to the CPHS office.

☐ D. "Identifiable Protected Health Information" The project involves the collection of Identifiable Protected Health Information. Continue to #5.

5. Are you requesting a **waiver for obtaining informed consent** (authorization) from patients?

☐ YES ☐ NO - If NO, attach the Consent Form.

If YES, provide an explanation of why the research could not practicably be conducted without the waiver of informed consent and without access to this data. Include a statement as to whether such a waiver will adversely affect the privacy rights and welfare of individuals:

Assurance:

My signature below provides written assurance from the PI that PHI will not be reused or disclosed to any entity outside of the PI's organization, except as required by law. The PI further agrees that if PHI is disclosed outside of the PI's organization without patient consent, a tracking (accounting) process is required. Contact the CPHS office for more information.

_____ _____

PI Signature Date

Data Use Agreement (for studies utilizing a Limited Data Set):

This submission provides assurance that the Researcher agrees:

- to the use of the limited data set or PHI to the specified purpose as described above
- to limit who can use or receive the data to the research team directly involved in this project
- not to re-identify the data or contact the individuals to whom the data belongs

Send this completed form to the CPHS Office via Researcher Email or hard copy with

Researcher Signature / Date: _____

Limited Data Set

The limited data set permits the retention of some identifying items not found in the "de-identified" list.

Not Allowed	Allowed
Names	Admission Dates
Street Addresses	Discharge Dates
Telephone and Fax Numbers	Service Dates
E-Mail Addresses	Death Date
Certificate or License Numbers	Age (including 90 or over)
Vehicle ID and Serial Numbers	Five Digit Zip Codes
URLs and IP Addresses	
Full Face Photos and Comparable Images	
Social Security Number	
Medical record number	

De-Identified Data: In order to be considered "De-identified data" the data collected may not contain any of the following items or a qualified statistician must verify methods as outlined below:

- Names
- Geographic subdivisions smaller than a state
- Zip codes*
- Dates (birth, admission, discharge, death)
- Age, if over 89
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate and license numbers
- Vehicle identification and serial numbers
- License plate numbers
- Device identifiers and serial numbers
- URLs
- Internet Protocol address numbers
- Biometric identifiers (finger and voice prints)
- Full face photos and comparable images
- Any other unique identifiers

*The first 3 digits of a zip code can be retained if publicly available data from the Bureau of the Census indicates that the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and the initial 3 digits of a zip code of all such geographic units containing 20,000 or fewer people is changed to 000.

Statistical Review Waiver 45 CRF 164.514(b)(1)

- A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;
- Determines that the risk of re-identification of the data, alone or in combination with other reasonably available data, is very small; and
- Documents the methods and results of the analysis to justify the determination.

Statistical Review:

_____ Printed name _____ Signature

Attachment B

Waiver of Informed Consent

1. For certain types of public benefit programs

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

2. For certain minimal risk studies:

Federal regulations allow an IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

PIs may request an alteration or waiver to the consent process provided their study meets the above criteria. In the Protocol Summary or Expedited Review Form, the PI needs to describe why the study meets these criteria. CPHS members reviewing the study materials will make a final determination if the consent process can be waived or altered based on the federal guidelines and information provided by the PI.

Please note: Studies requesting an alteration/waiver of consent procedures for studies involving protected health information may also be subject to HIPAA regulations. If the study you are proposing is a medical records/chart review study, please use the Medical Records/Chart Review Study form in Attachment C.

Attachment C
Waiver of Signed Consent

Federal regulations provide for the waiver of signed documentation of consent as described below:

The CPHS may waive the requirement to obtain a signed consent form for some or all subjects if:

(1) The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

OR

(2) That the research presents no more than minimal risk of harm to subject and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, The CPHS may require the investigator to provide subjects with a written statement (information sheet) describing the research.

PIs may request a waiver to documented consent provided the study meets the above criteria. In the Protocol Summary or Expedited Review Form, the PI shall describe why the study meets these criteria. CPHS members reviewing the study materials will make a final determination if documentation of consent can be waived or altered based on the federal guidelines and information provided by the PI.